

# Real-world Evidence on Diagnosed Gastroparesis in Europe: Multi-database Observational Epidemiological Study (TAK-906-5003)

**First published:** 19/02/2021

**Last updated:** 25/03/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS37806

### Study ID

49349

### DARWIN EU® study

No

### Study countries

☐ Finland

☐ Spain

## Study description

The study will provide information about people with gastroparesis.

The main aims are to estimate the number of new cases of gastroparesis during a specific time and to estimate the total number of cases of gastroparesis.

Cases of gastroparesis will be found from records held in large healthcare databases, based on information on diagnoses, test results, and treatment for the condition.

Children, teenagers, and adults will be included in the study.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

**IQVIA**

☐ United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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#### Study contact

[trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

#### Primary lead investigator

Fabian Hoti

#### Primary lead investigator

## Study timelines

#### Date when funding contract was signed

Planned: 12/06/2019

Actual: 12/06/2019

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#### Study start date

Planned: 22/02/2021

Actual: 25/02/2021

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#### Date of final study report

Planned: 30/09/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

To assess the incidence and prevalence of gastroparesis in the populations in countries of interest and to describe patients with gastroparesis in terms of their characteristics incl. socio-demographic characteristics, etiologic factors, clinical characteristics, diagnostic and treatment practices.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Impaired gastric emptying

## Population studied

### **Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Estimated number of subjects**

9000000

## Study design details

## **Outcomes**

The primary outcome for the analyses of incidence and prevalence will be gastroparesis, as identified using a case definition based on information on diagnoses and other clinical records, records of conducted tests and test results, procedures, and recorded pharmacological and non-pharmacological treatment.

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## **Data analysis plan**

Cases of gastroparesis will be identified using a case definition based on information on diagnoses and other clinical records, records of conducted tests and test results, procedures, and recorded pharmacological and non-pharmacological treatment.

For the analyses of occurrence of gastroparesis, the incidence rate and prevalence with 95% confidence intervals will be estimated. Incidence rates and prevalence will be reported overall and stratified by age group, sex, and calendar year.

For the analyses of characteristics of cases of gastroparesis, standard descriptive statistical method measures will be used, including mean, standard deviation, median, and distribution quartiles, number of non-missing observations, number of participants with missing data.

For categorical variables, the proportion and frequency of patients in each category level will be reported.

## **Data management**

## **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

**Data characterisation conducted**

No